This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

# PATIENT GROUP DIRECTION (PGD)

## Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

## in Leicestershire and Rutland County Councils

Version Number 2.0

| Change History | |
|---|---|
| **Version and Date** | **Change details** |
| Version 1.0 March 2020 | New template |
| Version 2.0 March 2023 | Updated template (no clinical changes to expired V1) |

## PGD DEVELOPMENT GROUP

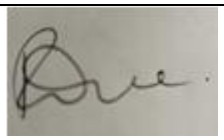
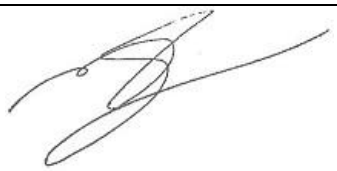
| | |
|---|---|
| Date PGD template comes into effect: | 1st March 2023 |
| Review date | September 2025 |
| Expiry date: | 28th February 2026 |
| Local review date | August 2024 |

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in October 2022.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

| Name | Designation |
|---|---|
| Dr Cindy Farmer | Chair General Training Committee<br>Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michelle Jenkins | Advanced Nurse Practitioner, Clinical Standards Committee<br>Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Vicky Garner | Deputy Chief Midwife British Pregnancy Advisory Service (BPAS) |
| Gail Rowley | Quality Matron British Pregnancy Advisory Service (BPAS) |
| Katie Girling | British Pregnancy Advisory Service (BPAS) |
| Julia Hogan | CASH Nurse Consultant MSI Reproductive Choices |
| Kate Devonport | National Unplanned Pregnancy Association (NUPAS) |
| Chetna Parmar | Pharmacist adviser Umbrella |
| Helen Donovan | Royal College of Nursing (RCN) |
| Carmel Lloyd | Royal College of Midwives (RCM) |
| Clare Livingstone | Royal College of Midwives (RCM) |
| Kirsty Armstrong | National Pharmacy Integration Lead, NHS England |
| Dipti Patel | Local authority pharmacist |
| Emma Anderson | Centre for Postgraduate Pharmacy Education (CPPE) |
| Dr Kathy French | Specialist Nurse |
| Dr Sarah Pillai | Associate Specialist |
| Alison Crompton | Community pharmacist |
| Andrea Smith | Community pharmacist |
| Lisa Knight | Community Health Services pharmacist |
| Bola Sotubo | NHS North East London ICB pharmacist |
| Tracy Rogers | Director, Medicines Use and Safety, Specialist Pharmacy Service |
| Sandra Wolper | Associate Director Specialist Pharmacy Service |
| Jo Jenkins (Working Group Co-ordinator) | Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service |

**ORGANISATIONAL AUTHORISATIONS**

| Name | Job title and organisation | Signature | Date |
|---|---|---|---|
| Dr Joshna Mavji | Consultant in Public Health, Leicestershire County Council |  | 10/08/2023 |
| Satyan Kotecha | Vice Chair and Clinical Pharmacist Community Pharmacy Leicestershire and Rutland |  | 08/08/2023 |
| Rajshri Owen | Chief Officer Community Pharmacy Leicestershire and Rutland |  | 09/08/2023 |
| Mike Sandys | Director of Public Health, Leicestershire County Council |  | 10/08/2023 |

## 1. Characteristics of staff

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| **Qualifications and professional registration** | Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation.<br><br>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.<br><br>Registered Pharmacists currently on the practising section of the pharmaceutical register held by the General Pharmaceutical Council that have completed the required training for accreditation and competency<br><br>Practitioners must hold a current and up to date Enhanced Disclosure and Barring Service check.<br><br>All healthcare professionals must be authorised by name under this direction before using it. |
| **Initial training** | The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy.<br><br>Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory.<br><br>Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme<br><br>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent. **See Appendix G** |
| **Competency assessment** | • Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for emergency contraception.<br><br>• Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions |
| **Ongoing training and competency** | • Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required.<br><br>• Organisational PGD and/or medication training as required by employing Trust/organisation. |
| The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies. | |

## 2. Clinical condition or situation to which this PGD applies

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| **Clinical condition or situation to which this PGD applies** | To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly. |
| **Criteria for inclusion** | • Any individual presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly.<br>• No contraindications to the medication.<br>• Informed consent given. |
| **Criteria for exclusion** | • Informed consent not given.<br>• Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines.<br>• Individuals 16 years of age and over and assessed as lacking capacity to consent.<br>• This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours.<br>• Known pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period).<br>• Less than 21 days after childbirth.<br>• Less than 5 days after miscarriage, abortion, ectopic pregnancy, or uterine evacuation for gestational trophoblastic disease (GTD).<br>• Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics<br>• Use of levonorgestrel (LNG-EC) or any other progestogen in the previous 7 days (i.e., hormonal contraception, hormone replacement therapy or use for other gynaecological indications).<br>• Concurrent use of antacids, proton-pump inhibitors or $H_2$-receptor antagonists including any non-prescription (i.e., over the counter) products being taken<br>• Severe asthma controlled by oral glucocorticoids.<br>• Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping.<br>• Acute porphyria |
| **Cautions including any relevant action to be taken** | • All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. |

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| | If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider.<br>• Ulipristal acetate (UPA-EC) is ineffective if taken after ovulation.<br>• If individual vomits within three hours from ingestion, a repeat dose may be given.<br>• Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC.<br>• Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of UPA-EC is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed.<br>• Breast feeding – advise to express and discard breast milk for 7 days after UPA-EC dose.<br>• The effectiveness of UPA-EC can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after UPA-EC. UPA EC is generally not recommended in a missed pill situation. See section 'Written information and further advice to be given to individual'.<br>• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.<br>• If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy.<br>• If the individual has not yet reached menarche, consider onward referral for further assessment or investigation. |
| **Action to be taken if the individual is excluded or declines treatment** | • Explain the reasons for exclusion to the individual and document in the consultation record.<br>• Record reason for decline in the consultation record.<br>• Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options. |

## 3. Description of treatment

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| **Name, strength & formulation of drug** | Ulipristal acetate 30mg tablet |
| **Legal category** | P |
| **Route of administration** | Oral |
| **Off label use** | Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).<br><br>This PGD includes off-label use in the following conditions:<br>• Lapp-lactase deficiency<br>• Hereditary problems of galactose intolerance<br>• Glucose-galactose malabsorption<br>• Severe hepatic impairment<br>Medicines should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.<br>Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence. |
| **Dose and frequency of administration** | • One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI. |
| **Duration of treatment** | • A single dose is permitted under this PGD.<br>• If vomiting occurs within 3 hours of UPA-EC being taken a repeat dose can be supplied under this PGD.<br>• Repeated doses, as separate episodes of care, can be given within the same cycle. Please note:<br>  ○ If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC)<br>  ○ If within 5 days of UPA-EC, then offer UPA-EC again (not LNG-EC) |
| **Quantity to be supplied** | Appropriately labelled pack of one tablet. |
| **Storage** | Medicines must be stored securely according to national |

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| | guidelines and in accordance with the product SPC. |
| **Drug interactions** | A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org<br><br>Refer also to FSRH guidance on drug interactions with hormonal contraception |
| **Identification & management of adverse reactions** | A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org<br><br>The following side effects are common with UPA-EC (but may not reflect all reported side effects):<br>• Nausea or vomiting<br>• Abdominal pain or discomfort<br>• Headache<br>• Dizziness<br>• Muscle pain (myalgia)<br>• Dysmenorrhea<br>• Pelvic pain<br>• Breast tenderness<br>• Mood changes<br>• Fatigue<br>• The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception. |
| **Management of and reporting procedure for adverse reactions** | • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk<br>• Record all adverse drug reactions (ADRs) in the patient's medical record.<br>• Report any adverse reactions via organisation incident policy. |
| **Written information and further advice to be given to individual** | • All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception.<br>• Ensure that a patient information leaflet (PIL) is provided within the original pack.<br>• If vomiting occurs within three hours of taking the dose, the individual should return for another dose. |

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| | • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception.<br>• Provide advice on ongoing contraceptive methods, including how these can be accessed.<br>• Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur.<br>• In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following UPA-EC use. Avoidance of pregnancy risk (i.e., use of condoms or abstain from intercourse) should be advised until fully effective.<br>• Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g., shorter, or lighter than usual), or if using hormonal contraception which may affect bleeding pattern.<br>• Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs.<br>• There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.<br>• Advise to consult a pharmacist, nurse, or doctor before taking any new medicines including those purchased. |
| **Advice / follow up treatment** | • The individual should be advised to seek medical advice in the event of an adverse reaction.<br>• The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned.<br>• Pregnancy test as required (see advice to individual above).<br>• Individuals advised how to access on-going contraception and STI screening as required. |
| **Records** | Record:<br>• The consent of the individual and<br>o If individual is under 13 years of age record action taken<br>o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.<br>o If individual over 16 years of age and not competent, record action taken<br>• Name of individual, address, date of birth |

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| | • GP contact details where appropriate<br>• Relevant past and present medical history, including medication history. Examination finding where relevant e.g., weight<br>• Any known medication allergies<br>• Name of registered health professional operating under the PGD<br>• Name of medication supplied<br>• Date of supply<br>• Dose supplied<br>• Quantity supplied including batch number and expiry date<br>• Advice given, including advice given if excluded or declines treatment<br>• Details of any adverse drug reactions and actions taken<br>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns<br>• Any referral arrangements made<br>• Any supply outside the terms of the product marketing authorisation<br>• Recorded that administered/supplied via Patient Group Direction (PGD)<br><br>Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.<br><br>All records should be clear, legible, and contemporaneous.<br><br>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

## 4. Key references

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| **Key references (accessed September 2022)** | • Electronic Medicines Compendium http://www.medicines.org.uk/<br>• Electronic BNF https://bnf.nice.org.uk/<br>• NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2<br>• Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - March 2017 (Amended March 2020) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/<br>• Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug- |

| | |
|---|---|
| | interactions-with-hormonal/<br>• Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines |

## Example registered health professional authorisation sheet

**PGD** PGDLRULI23 **Valid from:** 14/08/2023 **Expiry:** 28/02/2026
unless PGD updated and reissued post review date

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

### Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

| **I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.** | | | |
|---|---|---|---|
| **Name** | **Designation** | **Signature** | **Date** |
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### Authorising manager

| **I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named health care professionals who have signed the PGD to work under it.** | | | |
|---|---|---|---|
| **Name** | **Designation** | **Signature** | **Date** |
| | | | |

### Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

LCC will take all reasonable steps to prevent the loss, misuse, or alteration of your personal information. Your information will be held on the council's secure, internal systems. Only the people who need to see your personal information will be allowed access to it and data will be securely disposed of when it is no longer needed. We will not send your information outside of the UK

## Appendix B – Patient Information Leaflets – and further information for patients

Patient information leaflet can be found here –

- https://www.medicines.org.uk/emc/product/14200/pil#gref

Further information for patients -

- https://www.nhs.uk/conditions/contraception/emergency-contraception/
- https://www.healthforteens.co.uk/sexual-health/contraception/contraception-and-having-safe-sex-just-the-facts/?location=Leicestershire+and+Rutland

| Client Assessment and Record Form for supply of ulipristal acetate (UPA) or levonorgestrel (LNG) for Emergency Contraception - to be used in conjunction with the approved PGDs ref PGDLRULI23 and PGDLRLEV23 | | | | | |
|---|---|---|---|---|---|
| **Consultation Date** | | | | | |
| **Client Details** | | | | | |
| **Name** | | | | | |
| **Address (not mandatory)** | | | | | |
| **Postcode** | | | | | |
| **D. O. B.** | | **Age** | | | |
| **Ethnicity (circle which applies)** | | | | | |
| **White:** | British | Irish | Gypsy or Irish Traveller | Other White | |
| **Mixed/Multiple ethnic Group** | White and Black Caribbean | White and Black African | White and Asian | | |
| **Asian/Asian British** | Chinese | Indian | Pakistani | Bangladeshi | Other Asian |
| **Black/African/ Caribbean/ Black British** | African | Caribbean | Other Black | | |
| **Other** | Arab | Any Other | Not Stated | | |
| **Confidentiality statement** | | | | | |
| **This is a confidential service.**<br><br>**Whatever your age, you have a right to confidential advice.**<br><br>**We will not give information to anyone (even if you are under 16) – including parents, other family members, care workers, school, or your doctor, without your permission.**<br><br>**The only reason that we may have to consider passing on confidential information without your permission, would be to protect you or someone else from serious harm. We will always try to discuss this with you first.**<br><br>**Any information about you will be stored securely.** | | | | | |
| **Confidentiality discussed with client Y/N** | | | | | |

| Patient Competence & Confidentiality (Fraser Guidelines apply) |
|---|
| If under 16 years old, client must be assessed to be competent using Fraser Guidelines (Appendix D) and give verbal consent. |

| 1. Criteria for Competence (for supply all answers must be 'yes') | Yes | No |
|---|---|---|
| Does the client understand the advice that she has been given? | | |
| Has the client been encouraged to discuss the situation with her parent/guardian? | | |
| The young person is likely to continue having, Sexual intercourse with or without contraceptive treatment. | | |
| Is the client's physical and/or mental health likely to suffer unless she receives emergency contraceptive treatment? | | |
| Is providing contraceptive advice and treatment in the client's best interest? | | |

**If the answer to any of the above is NO then the client must be referred to her GP or the local Sexual Health Service as a matter of priority so that treatment may still take place within the necessary timeframe.**

**2. Have any safeguarding, including child sexual exploitation, concerns been identified? (Referral information is in Appendix F)**

**Suggested areas to consider:**

- **age difference between couple and age of partner**
- **where they met partner (internet/position of trust/via peers)**
- **how long they have been together?**
- **appears frightened of partner**
- **any learning disability**
- **understanding of abuse/coercion/exploitation**
- **existing social worker**

| **Has a safeguarding referral been made YES/NO** | |
|---|---|

**Detail here any additional information relevant to your decision to supply oral emergency contraception to this young person**

## Client History

**Details of current requirement for Emergency Contraception (tick all that apply)**

| | | | |
|---|---|---|---|
| **No contraception used** | | **Failure of barrier method** | |
| **Missed pill (give LNG only)** | | **Vomited EC dose** | |
| **Other – please state** | | | |
| **How long ago was UPSI (hours)? <72 hrs, 72-96 hrs, 96-120 hrs, >120hrs** | | | |
| **Self-reported Weight** | | **Self-reported Height** | **BMI =** |

| **Current regular method of contraception** | |
|---|---|
| **Condom** | |
| **Pill (specify type) If missed Pills, give details (give LNG only):** | |
| **IUD/S** | |
| **None** | |
| **Other (Specify)** | |

| **Menstrual cycle** | |
|---|---|
| **Day of cycle** | |
| **Usual cycle length (days)** | |
| **Regular Y/N** | |
| **Has client had LNG or UPA since the LMP? Y/N If LNG then give repeat LNG only** | |

**For supply of UPA, complete section A below.**
**For supply of LNG, complete section B below.**

## SECTION A: For UPA supply (PGD Ref PGDLRULI23)

### Inclusion Criteria

| | Y/N |
|---|---|
| **UPSI occurred within previous 120 hours? (Or within time judged to be clinically appropriate in relation to Cautions section of PGD)** | |
| **Where a client has vomited the dose of UPA, was this within 3 hours of ingestion?** | |
| **Have all options for Emergency Contraception been explained and the client prefers oral EC?** | |

### Exclusion/Caution criteria (including follow up action)

Appendix C Client Assessment and Record Form for print if required

| Criteria | Y/N | Recommended follow up | Follow up taken (please detail) |
|---|---|---|---|
| **Clients aged 13 years or under** | | • Use of professional judgement to consider supply of oral EC,<br>• There is a duty to seek further advice and onward referral to address child protection issues.<br>**The Child Protection Team must be contacted for children aged 13 or under who present having had sexual intercourse.** | |
| **Drug interactions** | | • Refer to earlier guidance in PGD Drug interactions | |
| **Breastfeeding** | | • FSRH recommends women can use UPA without restriction. Women to be advised not to breastfeed for a week / express and discard milk after UPA-EC | |
| **Vomiting** | | • If the request is due to an episode of vomiting which has occurred within 3 hours of taking the UPA dose, a replacement supply may be issued (see Appendix E). | |
| **Repeated use in same cycle** | | Advise client:<br>• She may be pregnant (consider pregnancy test as appropriate)<br>• Repeated use disturbs menstrual cycle<br>• Consider IUD as preferred alternative<br>• UPA will not interrupt a pregnancy (there is no epidemiological data to indicate that 30 micrograms UPA has an adverse effect on the foetus) | |
| **Episodes of UPSI over 120 hours** | | Consider referral for IUD up to 120 hours from likely ovulation. | |
| **Previous UPSI within the same cycle and treated with UPA** | | Consider providing UPA and referral for IUD. | |
| **Previous UPSI within the same cycle and treated with LNG** | | If within 7 days of LNG do not supply and refer to LNG PGD. If LNG was taken >7 days ago UPA can be supplied. Consider referral for IUD. | |
| **Severe hepatic dysfunction** | | Consider discussion with Integrated Sexual Health Service or GP. Pregnancy poses a significant risk in this group therefore expert opinion suggests use of UPA is acceptable. | |

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| **Possible pregnancy:**<br>• **Vague menstrual history**<br>• **Last menstrual period late/abnormal/different** | | • Consider pregnancy test.<br>UPA will not interrupt a pregnancy (there is no epidemiological data to indicate that 30 micrograms UPA has an adverse effect on the foetus) | |
| **Clients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption** | | Consider discussion with Integrated Sexual Health Service or GP. | |
| **Known acute porphyria** | | Consider discussion with Integrated Sexual Health Service or GP.<br>Refer to Sexual Health Service or GP asap. | |
| **Know hypersensitivity to UPA** | | Consider supply of LNG. Refer to GP or integrated sexual health service | |
| **Client Over 25 years of age** | | Offer purchase of OTC supply.<br>Refer to GP or sexual health services. | |
| **Administering oral EC after ovulation** | | Advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. Advise IUCD would be more suitable and refer to GP or sexual health service. Oral EC can still be issued in these circumstances in case this is an unusual cycle. | |

| **SECTION B: For LNG supply, if UPA is excluded (PGD Ref:PGDLRLEV23)** | | | |
|---|---|---|---|
| **Inclusion Criteria** | | | |
| **UPSI occurred within previous 96 hours? (Or within time judged to be clinically appropriate in relation to Cautions section of PGD)** | | | **Y/N** |
| | | | |
| **Where a client has vomited the dose of oral EC, was this within 3 hours of ingestion?** | | | **Y/N** |
| | | | |
| **Have all options for Emergency Contraception been explained and the client prefers oral EC?** | | | **Y/N** |
| | | | |
| **Missed pills are in the timescales that cause loss of protection?** | | | **Y/N** |
| | | | |
| **Exclusion/Caution criteria (including follow up action)** | | | |
| **Criteria** | **Y/N** | **Recommended follow up** | **Follow up taken (please detail)** |

| | | | |
|---|---|---|---|
| **Clients aged 13 years or under** | | • Use of professional judgement to consider supply of oral EC,<br>• There is a duty to seek further advice and onward referral to address child protection issues.<br>**The Child Protection Team must be contacted for children aged 13 or under who present having had sexual intercourse.** | |
| **Clients currently taking enzyme inducing drugs or have stopped within the last 28 days** | | May be offered 3000 microgram dose of LNG (this is not based on evidence or within product license but on expert clinical judgement of balance of risks and benefits) | |
| **Breastfeeding** | | FSRH recommends women can use progesterone-only emergency contraception without restriction. | |
| **Client weighs 70kg or has a BMI of over 26** | | FRSH recommends women offered 3000 microgram dose of LNG | |
| **Vomiting** | | If the request is due to an episode of vomiting which has occurred within 3 hours of taking the UPA dose, a replacement supply may be issued (see Appendix E). | |
| **Repeated use in same cycle** | | Advise client:<br>• She may be pregnant (consider pregnancy test as appropriate)<br>• Repeated use disturbs menstrual cycle<br>• Consider IUD as preferred alternative<br>• LNG EHC will not interrupt a pregnancy (there is no epidemiological data to indicate that 1500 micrograms LNG has an adverse effect on the foetus) | |
| **Episodes of UPSI over 96 hours and UPA exclusions apply** | | Consider referral for IUD up to 120 hours from likely ovulation. Consider pregnancy test. | |
| **Previous UPSI within the same cycle and treated with UPA** | | Consider providing UPA and referral for IUD. LNG must not be issued within 7 days of UPA | |
| **Severe hepatic dysfunction** | | Consider discussion with Integrated Sexual Health Service or GP. Pregnancy poses a significant risk in this group therefore expert opinion suggests use of a single dose of LNG 1.5mg is acceptable. | |
| **Known breast cancer** | | Consider discussion with Integrated Sexual Health Service or GP. | |

| | | | |
|---|---|---|---|
| **Severe malabsorption syndromes i.e., Crohn's** | | Consider discussion with Integrated Sexual Health Service or GP. | |
| **Possible pregnancy:**<br>• **Vague menstrual history**<br>• **Last menstrual period late/abnormal/different** | | Consider pregnancy test. | |
| **Clients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption** | | Consider discussion with Integrated Sexual Health Service or GP. | |
| **Client given birth in last 3 weeks** | | EHC <u>not</u> required. | |
| **Known acute porphyria** | | Consider discussion with Integrated Sexual Health Service or GP.<br>Refer to Sexual Health Service or GP asap. | |
| **Know hypersensitivity to levonorgestrel** | | Provide UPA if criteria met within PGD<br>Refer to GP or integrated sexual health service | |
| **Client Over 25 years of age** | | Offer purchase of OTC supply.<br>Refer to GP or Integrated sexual health services. | |
| **Administering oral EC after ovulation** | | Advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. Advise IUCD would be more suitable and refer to GP or sexual health service. Oral EC can still be issued in these circumstances in case this is an unusual cycle. | |

| **Action taken** | | |
|---|---|---|
| | **Y/N** | **Dosage (please specify)** |
| **Supply of ulipristal acetate** | | |
| **Supply of levonorgestrel** | | |
| **Patient consent given to share information with GP or Integrated Sexual Health Service (if required).** | | |

| | | | |
|---|---|---|---|
| **Record made on PMR & dispensing label provided** | | | |
| **Batch Number** | | **Expiry Date** | |
| **Comments:** | | | |
| **If supply is not given, please detail reason & onward referral action taken.** | | | |

## Advice/Follow up Check List (tick to confirm discussed/actioned)

| | |
|---|---|
| Effectiveness, including failure rate & advice re: abdominal pain | |
| inform re: side effects | |
| Action if vomit within 3 hours | |
| Next period may be early/late | |
| Return if further UPSI | |
| Pregnancy test in 3 weeks | |
| If oral EHC fails: not harmful to pregnancy | |
| Encourage contact GP Sexual Health clinic for regular contraception | |
| Medication taken on premises | |
| Manufacturer's patient information leaflet and Patient Information Sheet issued | |
| STIs discussed and ways to access a screen provided. (Sexual health service or online test kit) | |
| Condom/information pack/c-card info issued. c-card distribution if appropriate. | |

## Confirmation and Consent

The stated action was based on the information given to me by the client.

The client has consented to use of levonorgestrel outside of product license. (If applicable)

| | |
|---|---|
| **Name of Pharmacist** | |
| **Signature of Pharmacist** | |
| **GPhC number** | |
| **Date** | |
| **PHARMACY STAMP** | |

Robust systems must be in place to meet the legal requirements of the Data Protection Act 1998 and the safeguarding of personal data at all times.

**The Fraser Guidelines in practice**

If a client is believed to be under the age of 16 the pharmacist should**:**

- Assess the maturity of the client in terms of understanding any advice given
- Encourage the client to involve her parents
- Consider the effect on the physical or mental health of the client if advice or treatment is withheld
- Make a decision as to whether the client's best interests require the provision of contraceptive advice or supplies or both without parental consent

Where the pharmacist does not consider a young person meets the Fraser Guidelines a supply of levonorgestrel may not be provided. The pharmacist should recommend (and assist where necessary) the client to attend their GP or the Integrated Sexual Health Service.

## Fraser Competence – Clients Under 16 Years

Following the case of *Gillick* in 1986, the courts have held that children and young people under 16 who have sufficient understanding and maturity to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent for treatment (Gillick Competence), in accordance with Fraser Guidance.

In England, Wales, and Northern Ireland, in order to provide contraception to young people under 16 years of age without parental consent, it is considered good practice to follow the Fraser Guidelines/criteria [1]

## The Fraser Guidelines

1. The young person **Understands** the professional's advice. and has sufficient maturity to understand what is involved in terms of moral, social, and emotional implications.
2. The young person cannot be persuaded to inform their **Parents** nor will they allow notification to the parent that contraceptive advice was being sought.
3. The young person is likely to begin, or to continue having, **Sexual intercourse** with or without contraceptive treatment.
4. Unless the young person receives contraceptive treatment, their physical or mental health, or both, are likely to **Suffer**.
5. The young person's best **Interests** require them to receive contraceptive advice or treatment with or without parental consent.

**U-P-S-S-I** is a useful mnemonic to remember these five guidelines[2]

[1] https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-on-obtaining-valid-consent-in-srh/
[2] https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-on-obtaining-valid-consent-in-srh/

## Underage Sexual Activity [3]

The Age of Consent: The legal age for young people to consent to have sex is still 16, whether they are straight, gay, or bisexual.

The aim of the law is to protect the rights and interests of young people, and make it easier to prosecute people who pressure or force others into having sex they don't want.

Children under the age of 13 are legally deemed incapable of consenting to sexual activity and therefore all incidences of sexual behaviour involving children under 13 should be considered as a potential criminal or child protection matter.

In all cases where the sexually active child is under the age of 13, a referral (see Referrals Procedure) must be made to Children's social care and a full assessment undertaken in consultation with partner agencies, including the Police.

Where there are concerns that a young person may be at risk of sexual exploitation, a referral should be made to Children's social care in accordance with the Referrals Procedure; where the situation is an emergency, the local police should be contacted immediately.

**The following may indicate a relationship that could present a risk to the young person**

This list is not exhaustive and other factors may be needed to be taken into account:

- Whether the young person is competent to understand and consent to the sexual activity they are involved in
- The nature of the relationship between those involved, particularly if there are age or power imbalances
- Whether overt aggression, coercion or bribery was involved including misuse of substances/alcohol as a disinhibitor
- Whether the young person's own behaviour, for example through misuse of substances, including alcohol, places them in a position where they are unable to make an informed choice about the activity
- Any attempts to secure secrecy by the sexual partner beyond what would be considered usual in a teenage relationship
- Whether the sexual partner is known by the agency as having other concerning relationships with similar young people
- If accompanied by an adult, does that relationship give any cause for concern?
- Whether the young person denies, minimises, or accepts concerns
- Whether methods used to secure compliance and/or secrecy by the sexual partner are consistent with behaviours considered to be 'grooming'
- Whether sex has been used to gain favours
- The young person has a lot of money or other valuable things which cannot be accounted for

Although unlawful, mutually agreed sexual activity between under-16-year-olds of similar age would not generally lead to prosecution unless there was evidence of abuse or exploitation.[4]

[3] https://llrscb.proceduresonline.com/p_underage_sexual_act.html?zoom_highlight=sexual#5.-issues
[4] FSRH Clinical Guideline: Contraceptive Choices for Young People (March 2010, amended May 2019) - https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/

## Patient Group Direction – Emergency Contraception Referral by Community Pharmacist

Dear Doctor,

The named client below is considered to be unsuitable for issue of oral emergency contraception under the Leicestershire County & Rutland County Council's Patient Group Direction for Emergency Contraception due to reasons provided below. Please provide the necessary advice regarding emergency contraception and/or on-going health care.

| | |
|---|---|
| Client's name | |
| Date of Birth | |
| Date and time of consultation with Pharmacist | |
| Details of client history and reason for referral | |
| Date of first day of LMP and day of cycle | |
| Length of normal cycle | |
| Hours since UPSI | |
| Normal method of contraception | |
| Any safeguarding concerns identified? Any actions taken? | |

Yours faithfully,
Pharmacist name:
GPHC number:
Pharmacy address:
Telephone number:

# Useful Contacts

| Organisation | Contact Details | |
|---|---|---|
| **LLR Sexual Health Service** for appointments, advice, information for patients | 0300 124 0102 | www.leicestersexualhealth.nhs.uk |
| **LLR Sexual Health Service** (Professional helpline) | 0300 124 0102 (option 4)<br><br>Available: Monday- Friday (9am -6.30pm) Saturday (9am – 1.30pm) | |
| **LLR Sexual Health Service** Prevention & Promotion Team for C-Card Scheme, pregnancy testing, advice, and information for young people | 0300 1240102 | www.leicestersexualhealth.nhs.uk |
| **Sexual Assault Referral Centre** (SARC) Juniper Lodge: | 0116 2733330 | www.juniperlodge.org.uk |
| **Rape Crisis** Jasmine House | 0116 2555962 | www.jasminehouse.org.uk |
| **Leicester Constabulary Sexual Assault Unit** (SIGNAL team/child abuse Investigation Unit) | Call 101<br><br>0116 222 2222 | |
| **Safeguarding**<br><br>**If you think a child or young person is being abused or harmed, act straight away.**<br><br>**If you have concerns about a child or young person, help is available 24 hours a day, seven days a week.** | **Leicestershire County Council**<br>**0116 305 0005**<br>Please complete the electronic Agency Referral Form which is available at the following link: https://www.leicestershire.gov.uk/leisure-and-community/community-safety/report-abuse-or-neglect-of-a-child<br><br>**Rutland County Council**<br>**01572 758407**<br>Referrals to social care about children must be made in writing or confirmed in writing (by fax) after telephone contact is made.<br><br>Postal address: Rutland County Council, Children's Duty & Assessments, Catmose, Oakham, Rutland, LE15 6HP<br><br>**Police**<br>**Non emergencies, call 101** | |

| | |
|---|---|
| | **In emergencies, always dial 999**<br><br>**ChildLine**<br>**0800 1111**<br>**www.childline.org.uk**<br><br>**NSPCC helpline**<br>**0808 800 5000**<br>**help@nspcc.org.uk**<br><br>**The Leicestershire and Rutland Local safeguarding Children Board procedures are available from: www.lrsb.org.uk**<br><br>**Leicester City safeguarding Children Board procedures are available from: www.lcitylscb.org** |

**All accredited pharmacists must have completed the following training.**

| | |
|---|---|
| NHSE eLearning for healthcare - Patient Group Directions programme | |
| CPPE Consultation skills for pharmacy practice: taking a patient-centred approach | |
| **CPPE Emergency hormonal contraception package including:**<br>Introduction to emergency hormonal contraception | |
| CPPE Emergency contraception workshop | |
| Emergency Contraception e-learning | |
| Safeguarding children Level 1 (eLearning for healthcare) | |
| Safeguarding children Level 2 (eLearning for healthcare) | |
| Safeguarding adults Level 1 (eLearning for healthcare) | |
| Safeguarding adults Level 2 (eLearning for healthcare) | |
| Consultation skills for pharmacy practice assessment | |
| Emergency contraception assessment | |

**Recommended Enhanced Learning**

| | |
|---|---|
| Health Education England Spotting the signs of child sexual exploitation | |

Individual accredited pharmacists must undertake the required training at least once every two years, as evidence of continuing professional development and maintenance of competence.

Local pharmacist training sessions delivered by the Integrated Sexual Health Service are available to book via the networking and training section of the integrated Sexual health Service website. (Link below) – You must attend the next session available after you have completed the training above. These sessions cover local safeguarding policies, offer scenario-based discussion, and deliver local networking opportunities.

Emergency Contraception Training (community-based service contracts) - Leicester Sexual Health